

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

**ULTRAGENYX PHARMACEUTICAL
INC., et al.,**

Plaintiffs,

v.

NAVINTA LLC, et al.,

Defendants.

Civil Action No. 24-9483 (ES) (MAH)

OPINION

This matter comes before the Court by way of the parties' March 28, 2025 joint discovery dispute letter. Joint Letter, March 28, 2025, D.E. 75. The parties disagree as to the inclusion of patent-prosecution bar—*i.e.*, a provision in the proposed Discovery Confidentiality Order that would bar any person who has access to confidential information from drafting or amending patent claims relating to triheptanoin before the Patent and Trademark Office, or any corresponding patent authority, for the duration of this litigation. *Id.* Defendants seek to include the additional language and Plaintiffs oppose. *Id.* The Court considers the dispute without oral argument pursuant to Federal Rule of Civil Procedure 78 and Local Civil Rule 78.1. For the reasons set forth below, Defendants' request is denied.

I. BACKGROUND

On September 26, 2024, Plaintiffs Ultragenyx Pharmaceutical Inc. ("Ultragenyx") and Baylor Research Institute d/b/a Baylor Scott & White Research Institute ("BRI") (Ultragenyx and BRI, together, "Plaintiffs") filed a Complaint for patent infringement against Defendants Navinta LLC ("Navinta"); Aurobindo Pharma Limited ("APL") and Aurobindo Pharma USA, Inc. ("Aurobindo USA") (APL and Aurobindo USA, together, "Aurobindo"); and Esjay Pharma

Private Limited (“EPPL”) and Esjay Pharma LLC (“Esjay Pharma”) (EPPL and Esjay Pharma, together, “Esjay”) (Navinta, Aurobindo, and Esjay, collectively, “Defendants”). Plaintiffs market a triheptanoin product called DOJLOVI®. Compl., Sept., 24, 2024, D.E. 1, ¶ 1. Plaintiffs asserted infringement of the claims of U.S. Patent No. 8,691,748 (“the ’748 patent”). *Id.*

On February 11, 2025, the Court held a pretrial scheduling conference pursuant to Federal Rule of Civil Procedure 16 and entered a Pretrial Scheduling Order. Pretrial Scheduling Order, Feb. 13, 2025, D.E. 54. The Court thereafter issued a First Amended Pretrial Scheduling Order. Am. Scheduling Order, Mar. 13, 2025, D.E. 69. The deadline to submit a proposed Discovery Confidentiality Order was set for March 21, 2025. *Id.* ¶ 6(a). The Court thereafter granted the parties’ extension requests to submit a proposed Discovery Confidentiality Order (“DCO”) on or before March 28, 2025. *See* Letter Order, Mar. 24, 2025, D.E. 73; Letter Order, Mar. 28, D.E. 76.

On March 28, 2025, the parties filed the instant dispute. Joint Letter, March 28, 2025, D.E. 75. Although the parties report that they have agreed on nearly all terms of the DCO, they remain at odds on whether the DCO should patent-prosecution bar language in paragraph 8 of the DCO. That part of paragraph 8 that is not in dispute is as follows:

8. All Confidential Information disclosed pursuant to this Order shall be used by a recipient thereof solely for the purposes of this litigation and not for any business, regulatory, commercial, or competitive purposes, including, but not limited to, filing or prosecuting patent applications, engaging in any post-grant patent proceeding, or any communicating or petitioning activity with the FDA or another regulatory agency. It shall be the duty of each party and each individual having notice of this Confidentiality Order to comply with this Order from the time of such notice. Subject to the other requirements of this Confidentiality Order, including this Paragraph 8, nothing herein shall prevent the

individuals identified in Paragraph 6 from participating in any post-grant proceedings at the PTO or in any foreign patent office or tribunal (including, but not limited to, ex parte reexamination, inter partes review, post-grant review, covered-business-method review, patent opposition proceedings, patent nullity proceedings, or patent invalidation proceedings).

Joint Letter, D.E. 75, at Attachment: Proposed Confidentiality Order, ¶ 8 (Defendants’ proposed language omitted). The patent-prosecution bar language that Defendants propose to include in paragraph 8, and to which Plaintiffs object, reads as follows:

For the duration of this action and a period extending one year thereafter, including appeals, the individuals identified in Paragraph 6 who have access to Confidential [I]nformation under this Order shall not engage, formally or informally, in drafting or amending patent claims relating to triheptanoin before the PTO or any corresponding authority For the avoidance of doubt, such individuals are permitted to participate in such post-grant proceedings as long as the individuals are not involved directly or indirectly in drafting or amending patent claims relating to triheptanoin.

Id.

Defendants contend that the proposed language is a necessary safeguard against the improper use of Defendants’ confidential information. *Id.* Plaintiffs, on the other hand, argue that the agreed-upon provisions already provide Defendants’ confidential information adequate protection, and a prosecution bar would impair Plaintiffs’ ability to litigate this case. *Id.* at 5.

II. LEGAL STANDARD

A party seeking a protective order must demonstrate good cause for its issuance. Federal Rule of Civil Procedure 26(c). In the context of a party seeking to include a provision effecting a patent prosecution bar, Federal Circuit law governs and applies the Rule 26 good cause standard. *In re Deutsche Bank Trust Co. Americas*, 605 F.3d 1373, 1378 (Fed. Cir. 2010). To establish good cause, “the party seeking to limit the disclosure of discovery materials must show that

‘specific prejudice or harm will result if no protective order is granted.’” *Vivus, Inc. v. Actavis Lab’ys FL, Inc.*, No. 14-3786, 2016 WL 590212, at *1-2 (D.N.J. Feb. 11, 2016) (quoting *In re Violation of Rule 28(D)*, 635 F.3d 1352, 1357-58 (Fed. Cir. 2011)).

Although a confidentiality order generally provides protection from the disclosure of sensitive information, “there may be circumstances in which even the most rigorous efforts of the recipient of such information to preserve confidentiality in compliance with the provisions of such a protective order may not prevent inadvertent compromise.” *Deutsche Bank*, 605 F.3d at 1378. The Court must therefore determine “whether an unacceptable opportunity for inadvertent disclosure exists” on a counsel-by-counsel basis according to the particular facts presented. *Id.* (quoting *U.S. Steel Corp. v. United States*, 730 F.2d 1465, 1467-68 (Fed. Cir. 1984)) (internal quotations omitted). A movant “must show that the information designated to trigger the bar, the scope of activities prohibited by the bar, the duration of the bar, and the subject matter covered by the bar reasonably reflect the risk presented by the disclosure of proprietary competitive information.” *Deutsche Bank*, 605 F.3d at 1381.

Courts retain “broad discretion” to decide what degree of protection is required, and “must balance this risk against the potential harm to the opposing party from restrictions imposed on that party’s right to have benefit of counsel of its choice.” *Id.* at 1380 (citations omitted). In assessing that balance, courts consider factors such as

the extent and duration of counsel’s past history in representing the client before the PTO, the degree of the client’s reliance and dependence on that past history, and the potential difficulty the client might face if forced to rely on other counsel for the pending litigation or engage other counsel to represent it before the PTO.

Id. at 1381.

If the movant satisfies that burden, the inquiry thereafter turns on an individual's involvement in "competition decisionmaking." *Id.* at 1378-81 (quoting *U.S. Steel*, 730 F.2d at 1467-68) (internal quotations omitted). The burden thus shifts to the party opposing the prosecution bar to show:

(1) that counsel's representation of the client in matters before the PTO does not and is not likely to implicate competitive decisionmaking related to the subject matter of the litigation so as to give rise to a risk of inadvertent use of confidential information learned in litigation, and (2) that the potential injury to the moving party from restrictions imposed on its choice of litigation and prosecution counsel outweighs the potential injury to the opposing party caused by such inadvertent use.

Deutsche Bank, 605 F.3d at 1381.

III. ANALYSIS

The Court agrees with Defendants that there is an opportunity for inadvertent disclosure, and, as such, proper precautions and restrictions within the DCO are appropriate. However, the Court does not find that Defendants have satisfied their burden of establishing good cause for the patent-prosecution bar. First, the agreed-upon language in the CO sufficiently addresses the potential risk of disclosure and prevents the use of Defendants' confidential information. Second, on balance, the potential risk of disclosure does not outweigh the potential harm to Plaintiffs' "right to have the benefit of counsel of its choice." *Id.* at 1380 (citations omitted).

Defendants assert that there is a high risk that their confidential information would be used improperly "because there is a pending patent application . . . in the same family as the asserted patents, and Plaintiffs could use Defendants' Confidential Information to amend the claims in that pending application to cover aspects of Defendants' proposed ANDA products." Joint Letter, March 28, 2025, D.E. 75, at 1. However, Defendants do not adequately explain why

the patent-prosecution bar is necessary to mitigate that risk. The agreed-upon language in paragraph 8 specifically prohibits that conduct by providing:

All Confidential Information disclosed pursuant to this Order shall be used by a recipient thereof solely for the purposes of this litigation and not for any business, regulatory, commercial, or competitive purposes, including, but not limited to, **filing or prosecuting patent applications**, engaging in any post-grant patent proceeding, or any communicating or petitioning activity with the FDA or another regulatory agency.

Id. at Attachment: Proposed Confidentiality Order, ¶ 8 (emphasis added). Under these terms, Plaintiffs’ utilization of the Defendants’ confidential information to amend a pending patent application would directly violate the DCO. Therefore, it is unclear what added benefit would come from Defendants’ additional language to prohibit Plaintiffs in-house counsel to draft or amend any patent claims relating to triheptanoin for the duration of this litigation and one year after.

Defendants also more broadly contend that the sharing of their Confidential Information would allow competitors to design around their patent claims, “create earlier competition in the market that would otherwise not have existed, and potentially enter the market before any Defendant.” *Id.* at 3. The Court is sensitive to any such risk. But that risk would be realized only if Plaintiffs violated the uncontested language of paragraph 8 by improperly utilizing Defendants’ confidential information for purposes other than this litigation. There is nothing to suggest Plaintiffs would violate the DCO. Defendants have failed to show the proposed bar “reasonably reflect[s] the risk presented by the disclosure of proprietary competitive information.” *Deutsche Bank*, 605 F.3d at 1381.

In contrast to Defendants’ speculative risk, the potential prejudice that the patent-prosecution bar poses to Plaintiffs is appreciable. Plaintiff Ultragenyx is a smaller

pharmaceutical company. Joint Dispute Letter, D.E. 75, at 5. Ultragenyx has a small in-house legal team and only one in-house counsel has responsibilities relating to DOJOLVI®. Adoption of the Defendants’ patent-prosecution bar would place Ultragenyx in the compromising position either: (1) precluding that attorney from overseeing this litigation in-house, and thereby depriving Ultragenyx from assisting outside counsel in its own legal representation; or (2) preventing Ultragenyx from overseeing its patent-prosecution matters, such as applications pending before the PTO. Following the Federal Circuit’s lead in *Deutsche Bank*, courts within the District of New Jersey and Third Circuit have consistently rejected patent-prosecution bars that pose such burdens on a patent litigant. *Deutsche Bank*, 605 F.3d at 1380-81; *Vivus, Inc.*, 2016 WL 590212, at *5; *Avion Pharms. LLC v. Granules Pharms., Inc.*, Civ. No. 20-898, 2021 WL 1785580, at *2 (D. Del. May 5, 2021).

Defendants contend that the proposed patent-prosecution bar would not unduly restrict Plaintiffs’ ability to litigate this matter. They propose that Plaintiffs’ counsel could either have Plaintiffs’ litigation counsel have exclusive access to Defendants’ Confidential Information, or Plaintiffs designate a different in-house counsel oversee this litigation. *See* Joint Dispute Letter, D.E. 75, at 2. But those alternatives pose the very prejudice inherent in depriving Plaintiffs of the “right to have the benefit of counsel of [their] choice.” *Deutsche Bank*, 605 F.3d at 1380.

See also Vivus, Inc., 2016 WL 590212, at *5.¹

¹ Defendants claim that the Undersigned has issued orders including the language they seek to include in the CO. *See* Joint Dispute Letter, D.E. 75, at 4 (citing *Azurity Pharms., Inc. v. Cosette Pharms., Inc.*, No. 23-3830, Jan. 14, 2023, D.E. 56, ¶ 8). However, in *Azurity*, all parties consented to the confidentiality order and the patent prosecution bar. Therefore, *Azurity* has little bearing on this matter.

The Court must strike a balance between “the risk of inadvertent use or disclosure of proprietary competitive information acquired during litigation” with the attorney’s importance in a party’s litigation interest. Here, the agreed-upon language of the DCO, and particularly paragraph 8, curbs Plaintiffs’ counsel’s use of confidential information, including as to ongoing patent prosecutions for triheptanoin-related applications. *Deutsche Bank*, 605 F.3d at 1381; *see* Joint Dispute Letter, D.E. 75, at Attachment: Proposed Confidentiality Order, ¶ 8 (“All Confidential Information disclosed pursuant to this Order shall be used by a recipient thereof solely for the purposes of this litigation and not for . . . filing or prosecuting patent applications . . .”). Therefore, on balance, Defendants’ generalized concern over the inadvertent disclosure of their Confidential Information is insufficient to overcome the prejudice that the additional language in the DCO would impose upon Plaintiffs.

IV. CONCLUSION

The Court therefore denies Defendants’ request to impose additional language in the Discovery Confidentiality Order. An appropriate Order accompanying this Opinion will be filed herewith.

s/ Michael A. Hammer
United States Magistrate Judge

Dated: June 5, 2025